K043128

September 2. 2004

SMDA 510(k) SUMMARY
OLYMPUS EndoArm

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

A. General Information

1. Applicant: & Manufacture

OLYMPUS Corporation
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(Registration Number : 9614612)

2. Submission Correspondent:

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3. Initial Importer :

OLYMPUS AMERICA INC.
Two Corporate Center Drive, Melville, NY 11747-9058
(Registration Number : 2429304)

4. Official Correspondent:

Laura Storms-Tyler
Director Regulatory Affairs and Quality Assurance
OLYMPUS AMERICA INC.
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E-mail : Laura Storms-Tyler@olympus.com
(Registration Number : 2429304)

B. Device Identification

1. Common/Usual Name : Neuroendoscope

2. Device Name : OLYMPUS EndoArm

3. Classification Name :

CFR Number	Classification Name	Class	Product Code
882.1480	Neurological endoscope	II	84 GWG

C. Identification of the predicate or legally marketed device(s)

The following listed devices are the predicate medical devices;

Model	510(k)#	Manufacturer	Class	Product Code
A7594A, A7595A, A7597A Neuroendoscope	#K971340	OLYMPUS Co,.	II	GWG
Endoscopic system for Lumber hernia discectomy	#k982133	OLYMPUS Co,.	II	HRX
Point Setter Holder for rigid endoscope and flexible endoscope	#K991989	Mitaka Kohki Co,. Ltd	II	GWG

D. Device Description

1. Summary

Subject device is a neurological endoscopy system, which consists of EndoArm, a stabilizing fixation component (adapter) and a family of rigid neurological endoscope. A number of component and accessories are also necessary for this system.

(1) EndoArm:

Mechanical

The Endoarm counter balance arm is designed to deliver smooth endoscope movement and steady fixation by use of compressed nitrogen gas to control the arm movement. The shape of the stand differs from the predicate device in that the predicate device is a bedside fixed design and subject device is a floor stand type. This allows physicians to move the endoscope near the target site only.

Illumination

The illumination is supplied by the Neuroendoscope through the light guide cable connected to the separate high intensity light source, OLYMPUS CLV-S40.
This light source utilizes a Xenon 300W bulb.

Imaging

Another significant difference from the predicate device is the ability of the EndoArm to manage image data from the Neuroendoscope and allow the user to adjust zoom, focus and rotate image. The physicians can operate the EndoArm from fine adjustment of the endoscope potion to image adjustment by one hand.

This feature is accomplished by the connection of the Neuroendoscope through the adapter (A81020A) on the EndoArm. The image from the distal end of Neuroendoscope is transmitted to the monitor via the CCD of OTV-S7V camera head, mounted in the EndoArm.

(2) Neuroendoscope (model: A81000A, A81001A, A81002A,A81010A, A81011A, A81012A, A81031A, A81032A, A81041A, A81042A)

Ten telescope models are discussed in this premarket notification. The range of specifications covers two different insertion diameters (ϕ 2.7mm / ϕ 4mm), five different working lengths (107mm/ 110mm / 112mm/134mm/ 137mm) and five different fields of view (0/ 30/ 70/ -30/-70 degree). The crank shaped endoscope offers the largest operation space and microscopic field. In summary, the subject Neuroendoscope models are substantially equivalent to the predicate Neuroendoscope (#k971340).

(3) Adapter (model: A81020A)

The subject device is an adapter for connecting the Neuroendoscope A810**A series to

the EndoArm stabilizing fixation device.

2. Design

EndoArm has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirement of IEC60601-1, IEC60601-1-1and IEC60601-2-18.

3. Materials

All the patient contacting materials used in this Telescope and ancillary equipment are identical materials that had cleared the past 510(k) submissions. And all materials have been confirmed with ISO 10993-1.

4. Intended Use of the device

The EndoArm system consists of the EndoArm, a stabilizing fixation(adapter), Neuroendoscope(A1***A series). A number of components and accessories are also necessary for this system.

(1) EndoArm

This product has been designed for manipulation and positioning of the Neuroendoscope during neurosurgery and spinesurgery.

(2) Neuroendoscopes (A81000A, A81001A, A81002A, A81010A, A81011A, A81012A, A81031A, A81032A, A81041A, A81042A)

The Neuroendoscopes are intended for use in observation and diagnosis of the brain ventricles and brain parenchyma, such as observation and diagnosis of cerebral aneurysms, hypophysis tumors, hematomas, brain tumors, cerebral vascular systems, cranial nerve and vascular compression syndromes as well as observation and diagnosis of lumber and cervical spine, such as herniated disc material, nerve roots and nucleus material

5. Comparison Technological Characteristics

(1) EndoArm

Items	EndoArm **(Predicate Device)**	Point Setter K991989 **(Predicate Device)**	Lumber hernia discectomy K982133 **(Predicate Device)**
Manufacture	OLYMPUS	Mitaka Kohki Co., Ltd	OLYMPUS
Materials contacts to patient	None	None	
Support system	Floor stand	Mounted on bed side	
Driving power	Compressed Nitrogen gas	Compressed Nitrogen gas	Manual
Attachment of TV camera	Attached to the Grip of the Arm	Attached to Endoscope directly	
Zooming	2 times	Not equipped	
Image rotation	360 degrees	Not equipped	

(2) Neuroendoscopes (Telescopes)

Item	Subject Device (A810***A series)	Predicate Device (A7594A,A7595A,A7597A)
Direction of View	0° : A81000A, A81010A 30° : A81001A, A81011A 70 ° : A81002A, A81012 A -30° : A81031A, A81041A -70° : A81032A, A81042A	0° : A7594A 30° : A7595A 70° : A7597A
Working Length	112mm : A81000A 110mm : A81001A, A81031A 107mm : A81002A, A81032A 137mm : A81010A ,A81011A, A81012 A, 134mm : A81041A, A81042A	158mm : A7594A, A7595A 155mm : A7597A
Outer Diameter	4mm : A81000A, A81001A, A81002A, A81031A, A81032A 2.7mm : A81010A, A81011A, A81012A, A81041A, A81042A	4mm: A7594A, A7595A, A7597A

6. Conclusion

When compared to the predicate devices, EndoArm does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.

Therefore the clinical data is not necessary for its evaluation of safety or effectiveness of the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

Olympus Corporation
c/o Mr. Neil E. Devine
Entela, Inc.
3033 Madison Avenue SE
Grand Rapids, Michigan 49548

Re: K043128
Trade/Device Name: Olympus EndoArm
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological endoscope
Regulatory Class: II
Product Code: GWG
Dated: December 14, 2004
Received: December 16, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043128

Device Name: OLYMPUS EndoArm

Indications For Use:

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- **EndoArm**
  This product has been designed for manipulation and positioning of the Neuroendoscope during Neurosurgery and spinesurgery.

- **Neuroendoscopes** (A81000A, A81001A, A81002A, A81010A, A81011A, A81012A, A81031A, A81032A, A81041A, A81042A)
  The Neuroendoscopes are intended for use in observation and diagnosis of the brain ventricles and brain parenchyma, such as observation and diagnosis of cerebral aneurysms, hypophysis tumors, hematomas, brain tumors, cerebral vascular systems, cranial nerve and vascular compression syndromes as well as intended for use in observation and diagnosis of the lumber and cervical spine, such as herniated disc material, nerve roots and nucleus material.

Prescription Use (Part 21 CFR 801 Subpart D) ___X___ AND/OR Over-The-Counter-Use (Part 21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043128